



DEPARTMENT OF HEALTH & HUMAN SERVICES

M 21871
New York District

Food & Drug Administration
300 Pearl Street, Suite 100
Buffalo, NY 14202

November 19, 1998

WARNING LETTER 1999-10

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Lawrence J. Stirpe, President
Luzro Pizza Empire, Inc.
d/b/a Lorenzo's Wholesale Foods
4278 Fay Road
Syracuse, New York 13219

Dear Mr. Stirpe:

An inspection of your facility was performed August 17-19, 1998 by U.S. Food and Drug Administration (FDA) Investigator David M. McNew. The inspection revealed fresh tuna loins processed at, and distributed from, your facility are adulterated within the meaning of Section 402(a)(4) of the Federal Food, Drug and Cosmetic Act. They are adulterated because your facility failed to operate in accordance with the requirements of Title 21, Code of Federal Regulations (21CFR) Part 123 "Safe and Sanitary Processing and Importing of Fish and Fishery Products".

As we explained in a previous letter to your firm, the seafood processing regulations, which became effective December 18, 1997, require implementation of a preventive system of food safety controls known as Hazard Analysis Critical Control Point (HACCP). HACCP essentially involves: (1) **identifying food safety hazards that, in the absence of controls, are reasonably likely to occur in your products;** and (2) **having controls at "critical control points" in the processing operation to eliminate or minimize the likelihood that the identified hazards will occur.**

Our inspection revealed your processing of fresh tuna loins deviates from the regulations contained in 21 CFR 123 as follows:

- failure to follow the monitoring procedures specified in your written HACCP plan for receiving scombrototoxin forming fish (including tuna) [21 CFR 123.6(b)]; and failure to maintain monitoring records for receiving scombrototoxin forming fish [21 CFR 123.6(c)(7)]. For fresh tuna received on ice, your HACCP plan calls for monitoring of, and documenting, the internal temperature of the fish upon receipt. At your facility this monitoring step is neither performed nor documented. Your plan also calls for monitoring of, and documenting, the adequacy of the ice inside the cartons in which the fish is received. At your facility there are no records to document either the performance, or the results, of any ice checks.

- failure to maintain sanitation control records for all production days [21 CFR 123.11(c)]; there were no sanitation control records for the time period 7/31/98 through 8/12/98. Sanitation monitoring records were found to be maintained generally for only the three busiest of six production days each week;

Additional failures requiring correction include the following:

- failure to perform calibration checks for the thermometer intended to be used to measure internal temperature of fish upon receipt, and for the temperature recorder chart used to monitor temperatures in the cooler [21 CFR 123.8(a)(2)(ii)].
- receiving monitoring records and sanitation control records fail to include the signature or initials of the person performing the operation [21 CFR 123.9(a)(3)];
- failure to review receiving monitoring records, and storage monitoring records (temperature recorder charts) on at least a weekly basis [21 CFR 123.8(a)(3)]; these records must be reviewed, signed, and dated, by an individual who has been trained in the application of seafood HACCP principles, within one week of the day the records are made;
- failure to have the HACCP plan for scombrototoxin forming fish signed and dated, either by the most responsible individual on site or by a higher level official of your firm [21 CFR 123.6(d)].

You should take prompt action to correct these and all violations at your firm. Failure to achieve prompt corrective action may result in further regulatory action - without further notice. These actions include seizure and/or injunction.

Please notify this office in writing, within 15 days, of the specific steps you have taken to correct the noted violations and to prevent a recurrence of similar violations. Your response should be directed to James M. Kewley, Compliance Officer, at the above address. His telephone number is (716) 551-4461 Ext. 3128.

Sincerely,


Brenda J. Holman
District Director